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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,973	06/09/2005	Bernhard Gutsche	C 2745 PCT/US	6953
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COGNIS CORPORATION PATENT DEPARTMENT 300 BROOKSIDE AVENUE AMBLER, PA 19002			EXAMINER OH, TAYLOR V	
			ART UNIT	PAPER NUMBER
			1625	
			MAIL DATE	DELIVERY MODE
			12/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,973

Applicant(s)

GUTSCHE ET AL.

Examiner

Taylor Victor Oh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/05</u> | 6) <input type="checkbox"/> Other: _____ |

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The Status of Claims:

Claims 13-25 are pending.

Claims 13-25 are rejected.

DETAILED ACTION

1. Claims 13-25 are under consideration in this Office Action.

Priority

2. It is noted that this application is a 371 of PCT/EP03/13563 (12/02/2003), which has a foreign priority document, Germany 10257525.8 (12/10/2002).

Drawings

3. The drawing filed on 6/09/2005 is accepted by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Amberlyst 17 as a heterogeneous catalyst, does not reasonably provide enablement for any catalysts generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

nearly connected, to include all kinds of heterogenous catalysts unrelated to the claimed invention commensurate in scope with these claims.

Furthermore, the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without **undue experimentation**.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation, citing *Ex Parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breath of the claims.

The Nature of the Invention

The nature of the invention in claim 13 is in the followings:

Claim 13 (New): A countercurrent process for the continuous esterification of C₁₋₂₂ fatty acids with C₁₋₁₀ monoalkanols, C₂₋₅ di- or trialkanols or mixtures thereof, said process comprising (a) partially reacting the fatty acids and alkanols in a preliminary reactor in the liquid phase in the presence of an heterogeneous catalyst,

The State of the Prior Art

The states of the prior art are described as followed:

Gabriel et al (U.S. Pat. No. 1,668,806) who prepared 1-butyl lactate by dehydrating 70% lactic acid with excess 1-butanol at 117° C., followed by addition of HCl catalyst, followed by refluxing and esterification with addition of excess 1-butanol and drawing a 1-butanol water azeotrope overhead. The process involved dehydration of the system and removal of water prior to the esterification step.

Bannister (U.S. Pat. No. 2,029,694) describes a method for producing esters that have boiling points of at least 120° C. The lactic acid and acidic catalyst are charged to a reactor

and heated to the boiling point of the ester or not less than 20° C. below this temperature. The alcohol is introduced into the reactor below the surface of the hot partially dehydrated acid. The ester, water of reaction, and excess alcohol are taken off overhead. For example, methyl lactate is formed at temperatures from 130 to 140° C. by introducing methanol into partially dehydrated lactic acid. The overhead distillate is 8–10% water, 42–42% methanol, and 50% methyl lactate, by weight. For every 4.8 moles of methyl lactate produced in the system a total of 17.9 moles of methanol is fed to the system. Most or all of the water taken overhead (5.0 moles) is produced by the esterification reaction. The effective feed water level is 0.2 moles. This means that the feed streams are essentially water free.

Weisberg et al (US 2,406,648) discloses the following summary process:

In general, a method in accordance with the present invention includes esterifying an alkali metal or alkaline earth metal lactate with a lower alkyl alcohol, the lactate ester of which is water-soluble such as, for example, methyl, ethyl, or isopropyl alcohol, in the presence of a strong mineral acid. During the formation of the ester, the action of the acid on the lactate salt unavoidably causes the formation of an alkali or alkaline earth metal salt, which with impurities in the lactate salt raw material forms a sludge which has the tendency to occlude and retain tenaciously a portion of the ester. The method of the present invention includes flash distillation of the ester, any excess alcohol and the water present or formed during esterification under conditions such that a clean separation of the liquid from the sludge is obtained. The liquid components may then be distilled to separate the alcohol from the aqueous solution of the ester and the water is then distilled off azeotropically to produce a substantially pure anhydrous ester.

Kahsnitz et al (US 5,177,229) discloses the process for the preparation of esters :

Alcohols and acids are esterified by means of liquid-phase equilibrium reactions on ion exchangers in an apparatus comprising a prereactor and a rectifying column with external reactors. The process is characterized by the fact that a portion of one of the starting compounds is fed directly to the external reactors.

As the prior art have been discussed in the above, there is no conclusive data that all kinds of heterogenous catalysts would be required to produce the final desired product except some acidic esterification catalyst, such as, a strong mineral acid, ion exchangers, etc..

The predictability or lack thereof in the art

In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that any catalyst would not work on the claimed process in the same way as the catalyst such as Amberlyst 17 disclosed in the specification. For example, Gardener (US 3,878,261) discloses the super acid catalyst of SbF_5 and $\text{CF}_3\text{SO}_3\text{H}$ used for isomerizing paraffins containing 4 to 12 carbons in a feed stream (see abstract page) ; furthermore, according to the text book, March's Advanced Organic Chemistry (March et al, 4th ed. 1992), it describes that another super acid, $\text{FSO}_3\text{H-SbF}_6$, is used in the formation of a carbocation, such as tert-butyl cation (see p. 219, the fourth paragraph) from isobutane unlike the claimed process.

Furthermore, the specification of the claimed invention does support the very idea of the unpredictable aspect of the catalysts by disclosing the specific and workable catalyst for the esterification in the above, not all kinds of the catalyst known in the art.

Moreover, chemical reactions are well-known to be unpredictable, *In re Marzocchi*, 169 USPQ 367, *In re Fisher*, 166 USPQ 18. Additionally, catalytic processes, such as are present here, are inherently unpredictable. The U.S. District Court District of Connecticut held in *MOBIL OIL CORPORATION v. W.R. GRACE & COMPANY*, 180 USPQ 418 that "there is an inherent mystery surrounding the unpredictability of the performance of catalysts; a mystery which is generally recognized and acknowledged by chemists in the cracking art. This is one more reason why the presumption of patent validity "should not be disregarded especially in a case of this sort where the intricate questions of [bio]chemistry involved are peculiarly within the

particular competence of the experts of the Patent Office." *Merck & Co. v. Olin Mathieson Chemical Corp.*, 253 F.2d 156, 164, 116 USPQ 484, 490 (4th Cir. 1958)". "The catalytic action can not be forecast by its chemical composition, for such action is not understood and is not known except by actual test, *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358, 368-369 (1928). Also see, *Application of Grant*, 304 F.2d 676, 679, 134 USPQ 248, 250-251 (CCPA 1962); *Rich Products Corp. v. Mitchell Foods, Inc.*, 357 F.2d 176, 181, 148 USPQ 522, 525-526 (2d Cir. 1966), cert. denied 385 U.S. 821, 151 USPQ 757 (1966); *Ling-Temco-Vought, Inc. v. Kollsman Instrument Corp.*, 372 F.2d 263, 268, 152 USPQ 446, 450-451 (2d Cir. 1967); *Georgia-Pacific Corp. v. United States Plywood Corp.*, 258 F.2d 124, 132-133, 118 USPQ 122, 128-129."

Therefore, from the above, it is clear that the use of a generic phrase "a heterogenous catalyst" can not ensure to form the desired claimed product in a good yield.

The amount of direction or guidance present

The direction present in the instant specification is that not any heterogenous catalysts can be led to the formation of the desired product. According to the specification, it is silent as to how any heterogenous catalysts can be led to the formation of the desired product and fails to provide guidance as to whether any heterogenous catalyst is sufficient enough to allow to form the desired product in

sufficient quantities; the specification fails to provide a correlation between the claimed process of the invention and the functional language of any heterogenous catalyst .

The presence or absence of working examples

In the instant case, the claim encompasses all the various heterogenous catalysts. Applicants' specification provide only one particular exemplified catalyst compounds ,such as Amberlyst 17 as shown in the specification (see pages 10-11). However, this can not be the representatives for all the heterogenous catalysts which would work for the claimed process. Thus, the specification fails to provide working examples as to how other types of heterogenous catalysts can be resulted in the claimed products, i.e. again, there is no correlation between the functional language of any heterogenous catalyst and the desired final product.

The breadth of the claims

The breadth of the claims is that any heterogenous catalyst would work on the claimed process in the same way as those disclosed catalyst in the specification without considering the affect or impact of the different types of catalysts on the starting compounds; for example, the super acid $\text{FSO}_3\text{H-SbF}_6$ disclosed in March's Advanced Organic Chemistry (March et al , 4th ed. 1992) has a high likelihood of removing hydrogen ions from the reactants, instead of helping them to form the desired product , thereby detrimentally affecting the yield of the desired final product.

The quantity of experimentation needed

The quantity of experimentation needed is large. One of skill in the art would need to determine which one of the catalysts would be capable of forming the desired

product and would furthermore then have to determine which one of the catalysts would not be resulted in the claimed desired compounds in a sufficient quantity.

The level of the skill in the art

Even though the level of skill in the esterification is high, the skilled artisan employing this process would be a BS chemist working in the a laboratory facility. He would know how to use the taught catalyst, but not how to select other catalyst without trail and error.

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which acidic catalyst can be employed to produce the desired claimed compound encompassed in the instant claims, with no assurance of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board

of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 24 recites the broad recitation "acidic clays, zeolites", and the claim also recites "specially worked up bleaching earths and catalysts based on transition metals" which is the narrower statement of the range/limitation. The examiner recommends to add those limitations to the dependent claims. Therefore, an appropriate correction is required.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kahsnitz et al (US 5,177,229) in view of Bremus et al (US 5,008,046) .

Kahsnitz et al discloses the process for the preparation of ester in the followings (see abstract):

Alcohols and acids are esterified by means of liquid-phase equilibrium reactions on ion exchangers in an apparatus comprising a prereactor and a rectifying column with external reactors. The process is characterized by the fact that a portion of one of the starting compounds is fed directly to the external reactors.

Due to the limited thermal stability of the acidic ion exchangers, esterification in the prereactor and in the external reactors is conducted at temperatures up to about 120° C. In so doing temperatures ranging from 40° to 100° C. are preferably used.

(see col. 3, lines 14-

18).

The instant invention, however, differs from the prior art in that the subsequent esterification reaction between the fatty acids and alkanols takes place using a reaction column in the presence of the catalyst after the initial esterification.

Bremus et al discloses the following esterification process (see col. 3, lines 2-

15):

component of the process is a reaction column 1, comprising a plurality of bubble plates, surmounted by the rectifying section 2. The catalyst or catalyst solution, optionally after heating, is delivered through a pipe 3 to the uppermost plate of the reaction column 1, as is the fatty acid (through a pipe 4), the fatty acid being heated by means of a heat exchanger 5 before delivery to the reaction column. The fresh alkanol is delivered through a pipe 6 to a second heat exchanger 7, superheated and directly introduced into the reaction column 1 through a pipe 8 immediately above the sump of the column. Fresh alkanol refers to alkanol which has not been recycled through the process.

Furthermore,

In another preferred embodiment of the invention, the esterification is carried out at a temperature at the top of the reaction column of at most 190° C. and more preferably in the range from 120° C. to 145° C. These esterification temperatures which are low by comparison with conventional processes lead in particular to a reduction in the necessary energy costs of the process. (see col. 2, lines 25-31).

Kahsnitz et al expressly the process of preparing esters from alcohols and acids by means of liquid phase reactions on ion exchangers in the prereactor and rectifying column along with external reactors; similarly, Bremus et al does disclose the use of the reaction column for the esterification process. Both processes are commonly involved in the esterification under a similar reaction such as a similar reaction temperature. Bremus et al does emphasize that a low esterification temperature in the use of the reaction column leads to a reduction in the necessary energy costs of the process. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to employ the Bremus et al reaction column in the Kahsnitz et al process in order to reduce the cost of the operation in the prior art process. This is because the skilled artisan in the art would expect or predict such a modification to be feasible and successful as guidance shown in the prior art.

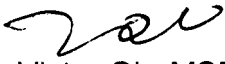
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Taylor Victor Oh, MSD, LAC
Primary Examiner
Art Unit: 1625

12/05/07